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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,110	12/02/2004	Shiroo Muraoka	61625 (70232)	1701
21874 7590 05/12/2009 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
JUNG, UNSU				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,110

Applicant(s)

MURAOKA ET AL.

Examiner

UNSU JUNG

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-12 and 14-17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3,5-12 and 14-17 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 08 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. The Examiner for the current application has been changed from David J. Venci to Unsu Jung in Art Unit 1641. Any inquiry concerning this application should be directed to Unsu Jung, whose contact information is provided in the conclusion section of this Office Action.

Response to Amendment

2. Applicant's amendments in the reply filed on September 29, 2008 have been acknowledged and entered. The reply included amendments to claims 1, 3, 5, 6, 12, 14, 15, and 17 and cancellation of claims 2, 4, and 13.

Status of Claims

3. Claims 1, 3, 5-12, and 14-17 are pending and currently under consideration for patentability under 37 CFR 1.104.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The instant application is a national phase application filed under 35 U.S.C. §371 from PCT Application No. PCT/JP2004/002604, filed on March 3, 2004, which claims priority to Japanese Patent Application No. JP 2003-340412, filed on September 30, 2003

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Japanese Patent Application No. JP 2003-340412 has been filed in the instant application.

Objections Withdrawn

5. The objection of the specification has been withdrawn in view of amended abstract in the reply filed on September 29, 2008.

Rejections Withdrawn

6. The following rejections have been withdrawn in view of amended claims 1 and 17 and canceled claims 2, 4, and 13 in the reply filed on September 29, 2008:

- Rejection of claims 1-11 under 35 U.S.C. 112, second paragraph;
- Rejection of claims 1, 4-7 and 11-17 under 35 U.S.C. 102(b) as being anticipated by Knowles & Marchesi;
- Rejection of claims 1, 4-7 and 9 under 35 U.S.C. 102(b) as being anticipated by Caldwell & Schacter;
- Rejection of claims 2, 3 and 8-10 under 35 U.S.C. 103(a) as obvious over Knowles & Marchesi in view of Powell; and
- Rejection of claim 1 under 35 U.S.C. 103(a) as obvious over Youngner & Noll (US 2,981,658) in view of Salk.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12 and all dependent claims thereof are vague and indefinite as claim 12 fails define the scope of the claim with respect to what unrecited additional components, or steps, if any, are excluded from the scope of the claim. Transitional phrases such as comprising, consisting essentially of, and consisting are typically used to define inclusive or exclusive nature of unrecited elements or method steps in the claim. See MPEP § 2111.03.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 12 and 14-17 rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Yeung et al. (U.S. PG Pub. No. US 2003/0044869 A1, published Mar. 6, 2003 and filed Sept. 4, 2001) (hereinafter "Yeung").

Yeung teaches a method and a kit (immunoassay kit) for the presence of a protein in a sample (see entire document, particularly p3, paragraph [0028]). Peanuts are one of the most common food allergies in both children and adults (p1, paragraph [0005]). Therefore, peanut proteins can be detected for food contamination testing purpose in food industry (p1, paragraph [0007]). The kit includes an antibody (the captive antibody) against whatever protein is being tested for, for example, an anti-peanut antibody (p3, paragraph [0028]).

With respect to claims 12 and 14-17, MPEP § 2113 states that the lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is

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eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Therefore, the immunoassay kit of Yeung reads on the currently recited antibody specific for peanut protein and kit comprising the antibody.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1, 3, 5, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowles et al. (U.S. Patent No. 4,658,022, Apr. 14, 1987) (hereinafter "Knowles") in view of Macri et al. (*Electrophoresis*, 2000, Vol. 21, pp1685-1693) (hereinafter "Macri").

With respect to claims 1, 3, and 5, Knowles teaches an immunoassay for detecting a water-sparingly-soluble/hardly extractable protein in a sample. The method involves immunizing an animal against an immunogen comprising a protein solubilized with an aqueous ionic surfactant such as sodium dodecyl sulfate (SDS) (column 9, lines 56-60, "immunizing a desired host animal with a suitably denatured form of a protein"; and column 8, line 15) and raising antibodies against the solubilized protein (column 9, lines 56-60, "examine the resulting immune response for antibodies exhibiting the desired increased specificity and/or avidity"; column 3, lines 14-18, "somatic cell hybridization techniques to obtain antibodies"). This method reads on the claimed step

(1) of extracting and/or solubilizing a water-sparingly-soluble/hardly extractable protein in a sample with an aqueous solvent containing an ionic surfactant such as SDS to provide a protein solution. The immunizing step of Knowles reads on the claimed step (2) of providing an immunogen for raising an antibody, against the water-sparingly-soluble/hardly extractable protein to be detected, wherein the immunogen is prepared by dissolving the water-sparingly-soluble/hardly extractable protein in an aqueous solvent containing the same ionic surfactant as that contained in the aqueous solvent of step (1) and claimed step (3) of preparing the antibody against the water-sparingly-soluble/hardly extractable protein to be detected by immunizing an animal with the immunogen provided in step (2) and obtaining the antibody from the immunized animal. Knowles further teaches a detection method, in which antibodies raised against the protein are added to the solubilized protein sample for determining binding of the antibody reagent to the protein (column 10, lines 17-18). Such detection method of Knowles reads on the claimed step (4) of adding the antibody to the protein solution of step (1) or a dilution of the protein solution of step (1) to form a reaction mixture, the claimed step (5) of incubating the reaction mixture of step (4) to form an antigen-antibody complex between the water-sparingly-soluble/hardly extractable protein and the antibody in the presence of ionic surfactant contained the aqueous solvent of step (1), and the claimed step (6) of detecting the formed antigen-antibody complex.

With respect to claims 6 and 7, Knowles teaches that the aqueous solvent in step (1) further comprises a reducing agent of 2-mercaptoethanol (column 8, line 23).

However, Knowles fails to teach a method, wherein the concentration of ionic surfactant in the aqueous solvent is higher than 0.3% w/v.

Macri teaches membrane protein solubilization method, in which SDS is used at 4% w/v (see entire document, particularly p1687, 2.2.4 *Protein solubilization of SR and SL fractions*), which reads on the claimed range of greater than 0.03% w/v.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art the time of the invention to employ the solubilization method of Macri, in which SDS is used at 4% w/v, in the method of Knowles in order to solubilize membrane proteins. One skilled in the art would have been motivated to employ a concentration of surfactant well known in the membrane protein chemistry arts in order to solubilize the membrane protein with a reasonable expectation of success.

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the concentration of ionic surfactant such as SDS in the aqueous solvent as greater than 0.03% w/v, greater than 0.3% w/v, or 1% w/v/ as currently recited in claims 1, 3, and 8, since it has been held that that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable ranges involves only routine skill in the art absent unexpected results. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382; *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

15. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowles (U.S. Patent No. 4,658,022, Apr. 14, 1987) in view of Macri (*Electrophoresis*, 2000, Vol. 21, pp1685-1693) as applied to claim 1 above, and further in view of Winkler et al. (U.S. Patent No. 5,645,838, July 8, 1997).

Knowles in view of Macri teaches an immunoassay for detecting the presence of a water-sparingly-soluble/hardly extractable protein in a sample as set forth above. However, Knowles in view of Macri fails to teach a method, further including an additional step of a boiling step.

Winkler teaches a method of solubilizing membrane protein by adding SDS boiling the solution for 5 minutes (see entire document, particularly columns 12-13, Example 6).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the denaturing/solubilizing method of Winkler in the method of Knowles in view of Macri in order to solubilize membrane proteins for further biochemical analysis. The advantage of adding an additional step, which further solubilizing the membrane proteins, provides the motivation to combine teachings of Knowles in view of Macri and Winkler with a reasonable expectation of success.

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to select an appropriate boiling temperature such as 80°C as recited in claims 10, since it has been held that that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable ranges involves

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only routine skill in the art absent unexpected results. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382; *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

16. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knowles (U.S. Patent No. 4,658,022, Apr. 14, 1987) view of Macri (*Electrophoresis*, 2000, Vol. 21, pp1685-1693) as applied to claim 1 above, and further in view of Yeung et al. (U.S. PG Pub. No. US 2003/0044869 A1, published Mar. 6, 2003 and filed Sept. 4, 2001).

Knowles in view of Macri teaches an immunoassay for detecting the presence of a water-sparingly-soluble/hardly extractable protein in a sample as set forth above. However, Knowles in view of Macri fails to teach a method, wherein the protein is a peanut protein.

Yeung teaches a method and a kit for the presence of a protein in a sample as set forth above.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the method of Knowles in view of Macri to detect peanut proteins of Yeung since peanut proteins can be detected for food contamination testing purpose in food industry. The advantage of detecting an

important food allergen in food industry provides the motivation to combine teachings of Knowles in view of Macri and Yeung with a reasonable expectation of success.

Response to Arguments

17. Applicant's arguments with respect to claims 1, 3, 5-12, and 14-17 have been considered but are moot in view of the new ground(s) of rejection.

Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/
Unsu Jung
Primary Examiner
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